



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,636	10/19/2001	Sidney T. Smith	FLM-5169	8615

7590 11/03/2006
MARK J. BUONAIUTO, ESQ.
BAXTER INTERNATIONAL INC.
LAW DEPARTMENT
ONE BAXTER PARKWAY, DF2-2E
DEERFIELD, IL 60015

EXAMINER

TRAN, THAO T

ART UNIT	PAPER NUMBER
----------	--------------

1711

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,636

Applicant(s)

SMITH ET AL.

Examiner

Thao T. Tran

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7, 9, 11-18, 20, 22, 23, 25, 28, 39-45, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 9, 11-18, 20, 22-23, 25, 28, 39-45, and 61-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2006 has been entered.
2. Claims 3-7, 9, 11-18, 20, 22-23, 25, 28, 39-45, and 61-62 are currently pending in this application. Claims 18 and 39 have been amended.
3. In view of the prior Office action, the rejections of the claims are maintained below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-7, 9-18, 20, 22-23, 25, 28, 39-45, and 61-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 18 and 39 have been amended to contain the recitation of “a single tie layer the second exterior layer”. There is nowhere in the specification that provide support for a “single tie layer” as originally presented.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 4-7, 9-18, 20, 22-23, 25, 28, 39-45, and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (US Pat. 6,361,843) as evidenced by DuPont.

8. From a prior Office action:

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Smith teaches a multiple layer structure having solution contact and outer exterior layers, where the outer layers are chosen from polyamides, polyesters, and polyolefins (abstract). The modulus of the overall film is less than 50,000 psi (col. 31 lines 18-28). Polyamide materials include ring-opening products nylon 6, nylon 12, or nylon 12, while condensation products nylon 66, nylon 6,10, and dimmer fatty acid polyamides are also included (col. 4 lines 1-14). Single-site catalyzed polyolefins are used, where ethylene-butene copolymers are preferred (col. 4 lines 57-67). Affinity and Exact materials are used, and the copolymers should have densities of 0.880-0.910 g/cc (col. 5 lines 1-3). Tie layers include blends of modified and unmodified polyolefins, where maleic anhydride is a preferred modifying agent (col. 5 lines 4-47). The thicknesses of the layers read on the applicant's claimed ranges (col. 5 line 66-col. 6 line 10).

Regarding slip agents, the reference does not require the use of such slip agents; thus, it is the examiner's position that the reference teaches structures essentially free of slip agents. The layers are coextruded and formed into medical containers (col. 6 lines 31-60).

Art Unit: 1711

Regarding the burst pressure of the films, it is noted that the prior art films are made of the same materials and thicknesses as employed by the applicant. Thus, it is the examiner's position that the structures would inherently possess the applicant's claimed burst pressure values.

Regarding the "in direct contact" or "directly contacting" language, the claims are interpreted in the broadest sense; the outer layer of Smith is attached directly to the inner layer through tie and barrier layers.

Regarding the "single tie layer" limitation, it is the examiner's position that any intermediate layers could be considered together as one tie layer, since they serve to bridge the first and second exterior layers to each other.

Regarding the newly added limitation, "only", the same arguments also apply since any intermediate layers could be considered together as one tie layer. It is noted that to distinguish the presently claimed tie layer from the prior art layers, the applicants should provide the chemical makeup of the layer that is different from the prior art.

9. Claims 4-7, 9-10, 14-18, 20, 22-23, 25, 28, 39-41, and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramesh et al. (US Pat. 6,610,392) as evidenced by MatWeb.

10. From a prior Office action:

Ramesh discloses multi-layered films comprising a polyolefin outer layer and an outer layer selected from polyester, polyamide, and polyurethane (abstract). The polyolefin layer comprises a single-site catalyzed homogeneous ethylene/a-olefin polymer having a preferred melting point below 100°C and a preferred carbon content of 4-8 carbons in the a-olefin (col. 11-col. 12 line 3). The polyolefin also preferably has a density of less than 0.898 g/cc to create a layer of up to 4-mil thickness (col. 15 lines 28-58', col. 16 lines 22-23). Materials for the other

Art Unit: 1711

outer layer include the applicant's claimed nylon materials at a thickness of up to 4 mils (col. 19 lines 22-28, .49-50). Tie layers are included at a thickness of 0.13 or 0.16 mils (col. 20 lines 16-20; example 1). The overall films have modulus values as low as 40,000 psi (col. 20 lines 42-50).

Regarding slip agents, the reference does not require the use of such slip agents; thus, it is the examiner's position that the reference teaches structures essentially free of slip agents. The layers are coextruded and formed into packaging containers (col. 1 lines 7-11., examples).

Regarding the burst pressure of the films, it is noted that the prior art films are made of the same materials and thicknesses as employed by the applicant. Thus, it is the examiner's position that the structures would inherently possess the applicant's claimed burst pressure values.

Regarding the "in direct contact" or "directly contacting" language, the claims are interpreted in the broadest sense, the outer layers of Ramesh are attached directly to each other through tie and intermediate layers.

Regarding the "a single tie layer" limitation, the reference appears to teach a single tie layer. Also, any intermediate layers could be considered together as one tie layer, since they serve to bridge the first and second exterior layers to each other.

Regarding the newly added limitation, "only", the same arguments also apply since any intermediate layers could be considered together as one tie layer. It is noted that to distinguish the presently claimed tie layer from the prior art layers, the applicants should provide the chemical makeup of the layer that is different from the prior art.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 11-13 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramesh in view of Adur et al.

13. From a prior Office action:

Ramesh applies as above, teaching the use of tie layers but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(a-olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EvoH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65, examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Ramesh's invention to improve the adhesive strength between the polyolefin and polar substrate.

14. Claims 3 and 62 are rejected under 35 U.S.C. 103(a) as being obvious over Smith et al. in view of Mueller.

15. From a prior Office action:

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a

Art Unit: 1711

showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104. together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP 706.02(1)(1) and 1 706.02(1)(2).

Smith applies as above, teaching specific polyamides and also teaching copolyesters for use as outer layers but failing to note the use of the applicant's claimed polyester ethers. Mueller teaches multilayer films for flexible container purposes, where Ecdel materials are taught as equivalent to nylon 66, nylon 6,10, and nylon 12 as materials providing improved heat resistance and abuse resistance (col. 9 lines 37-53). Ecdel materials are noted by the applicant as PCCE polymers. It is the examiner's position that it would have been prima facie obvious to use PCCE polymers as outer layers in Smith's invention to provide multilayer films having equally improved heat resistance and abrasion resistance.

16. Claims 3 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramesh et al. '392 in view of Mueller.

17. From a prior Office action:

Ramesh applies as above, teaching specific polyamides and also teaching polyesters for use as outer layers but failing to note the use of the applicant's claimed polyester ethers. Mueller teaches multilayer films for flexible container purposes, where Ecdel materials are taught as equivalent to nylon 66, nylon 6,10, and nylon 12 as materials providing improved heat resistance and abuse resistance (col. 9 lines 37-53). Ecdel materials are noted by the applicant as PCCE

Art Unit: 1711

polymers. It is the examiner's position that it would have been prima facie obvious to use PCCE polymers as outer layers in Ramesh's invention to provide multilayer films having equally improved heat resistance and abrasion resistance.

Response to Arguments

18. Applicant's arguments filed on 8/25/2006 have been fully considered but they are not persuasive.

Applicants contend that the references teach away from the presently claimed invention because they teach additional layers between the exterior layers. As previously stated, the claims are interpreted in their broadest sense to allow for intermediate layers. The exterior layers of the references are directly attached through intermediate layers. In the case of the Smith reference, the exterior layers are attached directly through intermediate sublayers, where the tie/core/tie structure constitutes a single tie layer. This same logic applies to the Ramesh reference. Again, it is the examiner's position that "in direct contact" or "directly contacting" encompasses the presence of intermediate layers. It is the examiner's position that a tie layer can contain sublayers, and so a "single tie layer" can include intermediate sublayers. By its broadest interpretation, a "tie layer" includes any intermediate layer connecting the two exterior layers. The same arguments also apply regarding the newly added limitation, "only" since any intermediate layers could be considered together as one tie layer. It is noted that to distinguish the presently claimed tie layer from the prior art layers, the applicants should provide the chemical makeup of the layer that is different from the prior art.

19. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

Art Unit: 1711

teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Mueller is used to illustrate that the use of PCCE as an alternative of polyamide in the exterior layer has been taught in the prior art. And Adur is used to illustrate the adhesive blends.

Contact Information

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1711

A handwritten signature in black ink, appearing to read 'Thao T. Tran'.

Thao T. Tran
Primary Examiner
Art Unit 1711

tt
October 27, 2006